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UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON

LARRY I. NEWKIRK and RUTH A. )  
NEWKIRK, )

Plaintiffs, )

vs. )

CONAGRA FOODS, INC., et al., )

Defendants. )

No. CV-08-273-RMP

MEMORANDUM OF AUTHORITIES  
IN SUPPORT OF DEFENDANTS'  
JOINT MOTION TO EXCLUDE THE  
SPECIFIC CAUSATION TESTIMONY  
OF PLAINTIFFS' EXPERT DR.  
EGILMAN

Defendants ConAgra Foods Incorporated, Symrise, Inc. and Chr. Hansen, Inc. (collectively "Defendants") file this Memorandum of Authorities in Support of their Motion to Exclude the Specific Causation Testimony of Plaintiffs' Expert Witness Dr. Egilman. Gregory J. Arpin, counsel for defendant ConAgra Foods, Inc. and the filer of this memorandum, confirms that the content of this document is acceptable to all persons whose electronic signatures appear below.

**I. SUMMARY OF ARGUMENT**

This is a toxic tort case in which Plaintiffs allege that Larry Newkirk was exposed to butter flavor microwave popcorn vapors (hereinafter "MWPC vapors") that he popped as a consumer, and that such exposure caused him to develop bronchiolitis obliterans ("BO") and other respiratory ailments. Plaintiffs apparently

1 offer the testimony of Dr. Egilman to establish specific causation, in addition to  
2 general causation, despite the absence of any scientific evidence of general  
3 causation, despite the fact that no one has established a safe level of MWPC vapor  
4 exposure, despite the fact that he has not attempted to determine Mr. Newkirk's  
5 actual exposures, and despite the fact that he failed to rule out other possible causes  
6 of Mr. Newkirk's disease. Dr. Egilman disregards this lack of reliable scientific  
7 evidence and instead proffers his own speculative and untested theory of causation.

8 Dr. Egilman's methodology can be succinctly summarized: (1) Newkirk has  
9 Bronchiolitis Obliterans (hereinafter "BO");<sup>1</sup> (2) Newkirk claims to have popped  
10 and consumed anywhere between two and five bags of popcorn a day for eighteen  
11 years;<sup>2</sup> (3) there is some evidence of some workers who were exposed to heated

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12  
13 <sup>1</sup> Dr. Egilman now appears to be changing his diagnosis to Bronchiolitis Obliterans  
14 Syndrome ("BOS").

15 <sup>2</sup> Artificial butter flavor with high levels of diacetyl came to be used by the MWPC  
16 industry in 1995. *Exh. DD, Lockey Study* at 63. Exhibit DD is authenticated by  
17 the Declaration of Elizabeth J. Citurs in Support of Defendants' Joint Motions to  
18 Exclude Expert Testimony and Dispositive Motions ("Citurs Declaration"), filed  
19 concurrently herewith. Each reference in this Memorandum of Authorities in  
20 Support of Defendants' Joint Motion to Exclude the Specific Causation Testimony  
21 of Plaintiffs' Expert Witness Dr. Egilman to "*Exh. H, Parmet Depo*" refers to  
22 Exhibit H attached to the Citurs Declaration filed in support of defendants' motions  
23 to exclude the testimony of plaintiffs' expert witnesses under *Daubert* and  
24 defendants' joint motions for summary judgment.

1 slurry mixtures containing butter flavorings (hereinafter “slurry” vapors) in an  
2 occupational setting - an entirely different exposure than that of MWPC vapors -  
3 developing BO; therefore, (4) Newkirk’s disease was caused by his unknown and  
4 unquantified exposure to MWPC vapors.

5 Dr. Egilman’s opinion is inadmissible speculation because he has not  
6 provided any scientific support for his theory that slurry vapors have the same  
7 toxic effects as MWPC vapors, with their vastly different chemical compositions,  
8 he has not established a safe level of exposures to diacetyl, nor has he in any way  
9 applied the methodology of science to make the several leaps necessary to reach  
10 his conclusions. Dr. Egilman has failed to even attempt to quantify Mr. Newkirk’s  
11 exposure and has failed to adequately consider alternative causes or provide  
12 reasons why alternative causes can be ruled out.

13 Expert testimony cannot be based on a mere hunch. *Daubert v. Merrell Dow*  
14 *Pharms. Inc.*, 509 U.S. 579, 592-94. Because Dr. Egilman’s testimony is based  
15 upon speculation, assumptions, and erroneous data, it is unreliable, irrelevant, and  
16 fails to assist the jury. Accordingly, Dr. Egilman’s specific causation opinion  
17 should be excluded under Rule 702. *Id.*

## 18 **II. FACTUAL BACKGROUND**

19 In order to avoid unnecessary repetition, the factual background is contained  
20 in the Statement of Undisputed Material Facts in Support of Defendants’ Joint  
21 Motions to Exclude Testimony and Joint Dispositive Motions Pursuant to LR 56.1  
22 (hereinafter “SOMF”) and in the Memorandum of Authorities in Support of  
23 Defendants’ Joint Motion for Summary Judgment (hereinafter “SJ Brief”).

### 1 III. LEGAL STANDARD

2 As set forth more fully in the Memorandum of Law in Support of  
 3 Defendants' Joint Motion to Exclude the General Causation Testimony of  
 4 Plaintiffs' Expert Witnesses (hereinafter "General Causation Brief"), *Daubert v.*  
 5 *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), in combination with  
 6 Federal Rule of Evidence 702, set the standard for challenges to the admissibility  
 7 of expert testimony. Defendants do not challenge Egilman's qualifications as an  
 8 expert in occupational medicine,<sup>3</sup> but they do challenge the methodology he used  
 9 to arrive at his opinions. This brief addresses Dr. Egilman's specific causation  
 10 opinion. His general causation opinion is addressed in a separate motion.

### 11 IV. DR. EGILMAN'S SPECIFIC CAUSATION OPINION 12 IS NOT RELIABLE OR RELEVANT.

13 Specific causation is defined as "whether exposure to an agent was  
 14 responsible for a given individual's disease." *Henricksen v. Cononco Phillips Co.*,  
 15 605 F. Supp. 2d 1142, 1156 (E.D.Wash. 2009); *see also In re Hanford Nuclear*  
 16 *Reservation Litigation*, 292 F.3d at 1133 (specific causation "refers to whether a  
 17 particular individual suffers from a particular ailment as a result of exposure to a  
 18 substance."). Courts employ a four-part test to determine whether the chemical at  
 19 issue caused a particular disease or injury. *Henricksen*, 605 F. Supp.2d at 1156.  
 20 For Specific causation testimony to be admissible, an expert must establish the  
 21 following criteria:

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22  
 23 <sup>3</sup> Defendants do object to Dr. Egilman's qualification as an expert outside of his  
 24 areas of medical expertise. *See, e.g.,* SOMF at ¶ 58-68.

(1) the toxic substance at issue must have been demonstrated to cause in humans the disease or illness suffered by the plaintiff; (2) the individual must have been exposed to a sufficient amount of the substance in question to elicit the health effect in question; (3) the chronological relationship between exposure and effect must be biologically plausible; and (4) the likelihood that the chemical caused the disease or illness in an individual should be considered in the context of other known causes.

*Id.* Dr. Egilman's testimony does not, and cannot, satisfy these necessary criteria.

**A) Dr. Egilman can not demonstrate that Microwave Popcorn Vapors can Cause the Disease Mr. Newkirk Suffers From.**

This first prong of the specific causation test really is general causation; without general causation there cannot be specific causation. *Henricksen*, 605 F.Supp.2d at 1176. As discussed in the General Causation Brief, plaintiffs' experts have not established general causation. For purposes of evaluating the other elements of specific causation at issue, however, defendants will disregard the lack of proof of general causation and address Dr. Egilman's specific causation testimony by assuming that general causation has already been established.

**B) Dr. Egilman can not establish that Mr. Newkirk was exposed to a Sufficient Amount of Microwave Popcorn Vapors to Cause his Disease.**

A fundamental tenet of toxicology is that "the dose makes the poison." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1242 (11th Cir. 2005) ("Dose is the single most important factor to consider in evaluation whether an alleged exposure caused a specific adverse effect."); *Exh. Q, Ewing Depo* at 32:13-15. Even if a particular agent has been shown to cause disease at some exposure level, it cannot be presumed that *any* amount of exposure to that agent can cause disease. *See Henricksen*, 605 F. Supp.2d at 1165-66:

1 The use of the no safe level or linear “no threshold” model for  
2 showing unreasonable risk “flies in the face of the toxicological law  
3 of dose-response,” that is, that “the dose makes the poison,” which  
4 refers to the general tendency for a greater dose of a toxin to cause  
5 greater severity of responses in individuals, as well as greater  
6 frequency of response in populations.

7 *Id.* (citing Federal Judicial Center, Reference Manual on Scientific Evidence 4775  
8 (2d ed. 2000)).

9 Due to the importance of the dose-response relationship in toxic tort cases,  
10 “[s]cientific knowledge of the harmful level of exposure to a chemical plus  
11 knowledge that plaintiff was exposed to such quantities are minimal facts  
12 necessary to sustain the plaintiff’s burden[.]” *Allen v. Pennsylvania Eng’g Corp.*,  
13 102 F.3d 194, 199 (5th Cir. 1996). “When analyzing an expert’s methodology in  
14 toxic tort cases, the court should pay careful attention to the expert’s testimony  
15 about the dose-response relationship.” *Id.* The dose-response relationship is “[a]  
16 relationship in which a change in amount, intensity, or duration of exposure to an  
17 agent is associated with a change-either an increase or decrease-in the risk of  
18 disease.’ . . . The expert who avoids or neglects this principle of toxic torts without  
19 justification casts suspicion on the reliability of his methodology.” *McClain v.*  
20 *Metabolife Intern., Inc.*, 401 F.3d 1233, 1241-42 (11th Cir. 2005) (quoting Michael  
21 D. Green et al., *Reference Guide on Epidemiology*, in REFERENCE MANUAL ON  
22 SCIENTIFIC EVIDENCE 392 (Federal Judicial Center, 2d ed. 2000)).

23 Courts consistently require plaintiffs seeking to show that chemical exposure  
24 caused their disease to quantify exposure levels, excluding expert testimony that is  
25 not based upon reliable quantifications. *See e.g. Henricksen*, 605 F.Supp.2d at  
1157; *Moore v. Ashland Chem.*, 151 F.3d 269, 278-79 (5th Cir. 1998); *Mitchell v.*

1 *Gencorp*, 165 F.3d 778, 781 (10th Cir. 1999); *Edwards v. Safety-Kleen Corp.*, 61  
2 F. Supp. 2d 1354, 1357-58 (S.D. Fla. 1999). In other words, to prevail on his  
3 claim, Mr. Newkirk must not only establish the level of exposure to microwave  
4 popcorn vapors that is hazardous to human beings generally, but he must also  
5 establish his own level of exposure to compare to that threshold level. *Id.* Dr.  
6 Egilman has not established the level at which microwave popcorn vapors can  
7 cause illness in human beings, nor has he determined Mr. Newkirk's exposure  
8 level.

9 **1. The workplace studies do not establish a safe exposure level or**  
10 **Mr. Newkirk's exposure level.**

11 Dr. Egilman relies on various workplace studies to conclude that "levels of  
12 diacetyl exposure below and around 1 ppm can cause BO and other respiratory  
13 illness." *Exh. B, Egilman Report* at 25. Again, setting aside the fact that the  
14 workplace studies are not comparable to consumer exposures because of the  
15 qualitative differences between the two exposures, *see* SOMF at ¶¶ 69-80, SJ Brief  
16 at pp. 2-4, the levels of exposure that Dr. Egilman claims to have extracted from  
17 these inapplicable studies are also lacking in scientific validity. To reach the 1  
18 ppm number, Dr. Egilman cited the results of three plant studies with respect to  
19 quality assurance ("QA") workers. *Exh. B, Egilman Report* at 24-25. This reliance  
20 ignores the fact that no valid scientific study has found a link between QA workers  
21 and lung disease. *Exh. DD, Lockey Study* at 68.

22 Dr. Egilman also cited the NIOSH Study conducted at the Gilster-Mary Lee  
23 plant (hereinafter "Gilster Plant Study") and the NIOSH study conducted at  
24 ConAgra's Marion, Ohio plant (hereinafter "Marion Plant Study"), *Exh. B, Egilman*

1 *Report* at 24-25. However, in both instances, Dr. Egilman failed to take into  
2 account the numerous reasons why the data from these studies can not be  
3 extrapolated to determine consumer exposures. General Causation Brief at pp. 11-  
4 13. Finally, Dr. Egilman includes mention of an unnamed and undisclosed study  
5 where the mean average diacetyl air concentration was “under 0.001ppm, and 0 out  
6 of 3 workers had obstruction.” *Exh. B, Egilman Report* at 25. Obviously, this  
7 statistic does not support any kind of threshold since none of the workers had  
8 obstruction at the level cited. Thus, Dr. Egilman did not and cannot establish a  
9 safe level of exposure.

10 **2. Neither the EPA nor Aspen studies establish a safe exposure**  
11 **level or Mr. Newkirk’s exposure level.**

12 Dr. Egilman also improperly relies on two studies conducted to identify total  
13 mass emissions from microwave popcorn in his attempt to quantify consumer  
14 exposures. In 2007, the Environmental Protection Agency (“EPA”) conducted a  
15 study to identify[y] and quantif[y] chemical emissions released in the process of  
16 popping and opening a bag of microwave popcorn.” (hereinafter “EPA Study”) *Exh. W, EPA Study* at 701. The EPA Study specifically noted that it “was a source  
17 characterization study and the potential exposure to the compounds measured and  
18 any associated potential risks were not estimated.” *Exh., W, EPA Study* at 709  
19 (emphasis added). The study forced, trapped and measured all chemicals emitted  
20 from a bag of microwave popcorn during and after the popping process. *Exh, W,*  
21 *EPA Study* at 702-05. The study was not intended to evaluate potential risk to  
22 consumers, and cannot be so used, because in a consumer setting, only a small  
23



fraction of any emitted chemicals could actually be inhaled by the consumer.<sup>4</sup> *Exh. ZZ, Morris Report* at 9-11.

The second study Dr. Egilman relies on is one commissioned by ConAgra “to help ConAgra better understand what compounds and how much of each were potentially emitted by various flavored popcorns[.]” (hereinafter “Aspen Study”) *Exh. EEE, Aspen Study* at 2. As with the EPA study, the Aspen study was designed only to look at the potential emissions from microwave popcorn. *Id.* For all the reasons the EPA Report is not relevant to establishing risk to consumers, Dr. Egilman’s reliance on the Aspen report is similarly misplaced.

### 3. The Wayne Watson home “study” does not establish a safe exposure level or Mr. Newkirk’s exposure level.

Dr. Egilman apparently relies on unpublished measurements of diacetyl taken in Mr. Watson’s home. *Exh. B. Egilman Report* at 22-23. Dr. Egilman has never actually seen the data from these measurements.<sup>5</sup> *Exh. S, Egilman Depo* at

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<sup>4</sup> Significantly, although the EPA did not identify the specific microwave popcorn brands that it tested, the results showed that the unnamed brand yielding the highest level of emitted chemicals in the EPA study had more than 15,000% higher diacetyl emissions than the brand yielding the lowest level of emitted chemicals. *SOMF* at ¶¶ 93-94. Thus, the EPA study numbers can not be correlated to the specific brands of popcorn that Mr. Newkirk popped and consumed.

<sup>5</sup> Also unknown is the specific brand(s) of popcorn used to collect these data; however, the Watson complaint alleged that he consumed microwave popcorn sold

1 193:17-194:3. Plaintiffs' own expert witness, Mr. Ewing, questioned the  
 2 methodology used for taking the measurements in Mr. Watson's home. *Exh. Q,*  
 3 *Ewing Depo* at 143:20-144:16. Dr. Egilman notes that all of the measurements of  
 4 diacetyl taken in Mr. Watson's home were below detectable limits, yet he opines  
 5 that this somehow serves as a basis for concluding that diacetyl levels were just  
 6 below the limits of detection. *Exh. B, Egilman Report* at 23.

7 **4. None of Plaintiffs' Experts have, or can, Establish Mr.**  
 8 **Newkirk's Exposure Level.**

9 Dr. Egilman's Rule 26 report is dated September 15, 2009, and expressly  
 10 relied on Mr. Ewing's exposure opinions in his report dated September 14, 2009.  
 11 *Exh. B, Egilman Report* at 23. However, on December 14, 2009, Dr. Ewing issued  
 12 a supplemental report, acknowledging serious flaws in his original report. *Exh. G,*  
 13 *Ewing Supp. Report*. Significantly, Dr. Ewing revised his quantification estimates  
 14 to eliminate the highest number that was in the report upon which Dr. Egilman  
 15 relied and the only number above Dr. Egilman's purported threshold of 1 ppm. *Id.*  
 16 Dr. Egilman thus relied on exposure estimates that plaintiffs' own expert retracted.  
 17 With Mr. Ewing's elimination of the highest estimates, the remaining estimates are  
 18 all substantially below Dr. Egilman's 1 ppm threshold.

19  
 20 under the label "First Choice." *Exh. DDD, Watson Complaint* at ¶16. Presumably,  
 21 it was "First Choice" microwave popcorn that was tested in his home. Due to the  
 22 dramatic differences in diacetyl emissions among various types of popcorn, any  
 23 data generated in Mr. Watson's home thus cannot be compared to the emissions  
 24 from Mr. Newkirk's Act II microwave popcorn. *SOMF* at ¶ 93-94.

1 Plaintiffs' experts have testified that they are not capable of quantifying Mr.  
2 Newkirk's exposure:

3 Q. . . . With respect to Mr. Newkirk, you are not able to give an  
4 exposure figure for him either; is that correct?

5 A. It would be the same thing. I have not tried to do that. You would  
6 have to make a lot of assumptions, including assumptions about air  
exchange rates and volumes in spaces that he's in. You could do that,  
but the accuracy of it I think would be questioned.

7 *Exh. Q, Ewing Depo* at 161:13-21.

8 Q. . . . [W]ere you provided anything that would allow you to  
9 quantify in any way the amount of butter flavoring chemicals that Mr.  
Newkirk was exposed to from microwave popcorn?"

10 A. No.

11 *Exh. P, Pue Depo* at 163:4-8.

12 Q. Do you have any opinion or any knowledge as to how much  
13 diacetyl or flavor chemicals Mr. Newkirk likely inhaled in popping  
microwave popcorn at his house?

14 A. I could not quantitate it.

15 *Exh. H, Parmet Depo* at 50:19-23.

16 If Dr. Egilman cannot quantify Mr. Newkirk's total exposure to microwave  
17 popcorn, then *a fortiori* he can not quantify his exposure to Symrise or Chr.  
18 Hansen's butter flavoring. "I didn't go into a year by year assessment of which  
19 brands he popped, which years and the relative amounts." *Exh. S, Egilman Depo* at  
20 21. "I haven't even tried to – I haven't tried to do any sort of allocation of whose  
21 butter flavor was in which product." *Exh. Q, Ewing Depo* at 159.



1 diagnosis; however, that diagnosis failed to adequately consider all possible causes  
2 for Mr. Newkirk's disease.

3 **1. Dr. Egilman's diagnosis of BO is not supported by any other**  
4 **doctor, including plaintiffs' other medical experts, or by the**  
5 **objective medical evidence.**

6 Two of Mr. Newkirk's treating pulmonologists – the ones he hired to  
7 actually treat his condition, not to bolster his chances of winning this lawsuit –  
8 concluded that he does not have BO or BOS caused by MWPC vapors. Dr. Sanjay  
9 Agarwal, a pulmonologist at Pulmonary & Critical Care Medicine in Spokane,  
10 WA, evaluated Mr. Newkirk on October 24, 2007. Dr. Agarwal concluded that  
11 Mr. Newkirk “does not fit the criteria for consideration for popcorn lung  
12 disease[,]” instead diagnosing him with “obstructive lung disease given his  
13 significant history of smoking.[.]” *Exh. EE, Agarwal Letter.*

14 In August 2009, Mr. Newkirk saw, Dr. James Elmer of Spokane Respiratory  
15 Consultants (after he had filed this lawsuit, and after Dr. Egilman had diagnosed  
16 BO, and Dr. Parmet and Dr. Pue had diagnosed him with BOS caused by exposure  
17 to microwave popcorn vapors). Mr. Newkirk saw Dr. Elmer following an episode  
18 at the office of his primary care physician, Dr. Doering, during which he  
19 hyperventilated and was unable to complete PFT testing. Dr. Elmer completed a  
20 report of his visit with Mr. Newkirk on August 18, 2009, and was critical of the  
21 diagnosis by Mr. Newkirk's experts: “The pulmonary doctors he saw, basically  
22 evaluated him from a medical legal standpoint. They did not recommend  
23 treatment, but were evaluating him from more a standpoint of his legal issues.”  
24 *Exh. FF, Elmer Report.* Dr. Elmer felt that Mr. Newkirk's episode in Dr.

1 Doering's office was "related to a panic attack with hyperinflation rather than other  
 2 issues[.]" and that he has "dyspnea related to Hyperventilation syndrome[.]" (*Id.*)  
 3 This opinion was further memorialized in a progress note made by Dr. Doering  
 4 after he spoke with Dr. Elmer on September 19, 2009: "Dr. Elmer does not believe  
 5 the patient has bronchiolitis obliterans or popcorn lung, but actually severe case of  
 6 panic attacks." *Exh. GG, Doering 9/16/09 Notes.*

7 Of significance, not even the other experts hired by the plaintiffs diagnosed  
 8 Mr. Newkirk with BO. *Exh. C, Pue Report; Ex. D, Parmet Report.* Thus, Dr.  
 9 Egilman is the only doctor to have diagnosed Mr. Newkirk with BO related to  
 10 microwave popcorn vapor exposure. *Exh. B, Egilman Report; Exh. C, Pue Report;*  
 11 *Exh. D, Parmet Report; Exh. E, Parmet Supp. Report.* This fact alone casts serious  
 12 doubts on the reliability of Dr. Egilman's diagnosis.<sup>6</sup>

13 Mr. Newkirk's test results are not supportive of a diagnosis of BO related to  
 14 MWPC exposure. On July 6, 2009, PFT tests were administered to Mr. Newkirk  
 15 and his FVC was 84% of what is predicted for a man his age prior to the  
 16 bronchodilators (which is considered a normal result), and 108% of the predicted  
 17 value after. *Exh. HH, 07/06/09 PFT Results.* That is an increase of 24% with  
 18 bronchodilators. As discussed in the SOMF, one of the hallmarks of BO is that it  
 19 is not reversible upon administration of bronchodilators. SOMF at ¶ 113.

20 Similarly, Mr. Newkirk's chest scans are not supportive of a BO diagnosis.  
 21 On August 3, 2009, Mr. Newkirk had a CT chest scan and there was no evidence

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22  
 23 <sup>6</sup> As noted previously, there is some indication that Dr. Egilman may now be  
 24 abandoning his original diagnosis of BO.

1 of mosaic attenuation – another hallmark of BO. *Exh. II, CT Exam 8/3/09*; SOMF  
 2 at ¶ 117; *see also Exh. BBBB, Popcorn Lung and Bronchiolitis Obliterans: A*  
 3 *Critical Appraisal* (“With the exception of mosaic pattern, there [is] no significant  
 4 difference in the presence of the HRTC findings . . . between severe asthma . . .  
 5 and BO.”). On February 2, 2008, Mr. Newkirk had a CT chest scan which  
 6 concluded that “[b]asilar predominant changes of emphysema with paucity of  
 7 pulmonary vasculature in the absence of bullous change is suspicious of panlobular  
 8 emphysema.” *Exh. JJ, CT Exam 2/2/08*.

9 Mr. Newkirk has many other symptoms suggestive of a smoking-related  
 10 disease, as Dr. Pue was forced to concede during his deposition. Mr. Newkirk has  
 11 an obstructive pattern (as opposed to restrictive or mixed), *Exh. P Pue Depo* at  
 12 99:5-100:8, his lung volume increased, *Exh. P, Pue Depo* at 89:9-23, he has air  
 13 trapping, *Exh. P, Pue Depo* at 111:20-112:10, he has hyperinflation, *Exh. P, Pue*  
 14 *Depo* at 112:4-113:4, Mr. Newkirk has evidence of bullae, *Exh. III, 08/14/08 CT*  
 15 *Scan*; *Exh. SS, Utell Report*; *Exh. P, Pue Depo* at 123:9-21, and his lung function  
 16 showed reversibility with bronchodilators. *Exh. P, Pue Depo* at 92-93. Each of  
 17 these factors supports a diagnosis of a smoking-related disease, and runs counter to  
 18 a diagnosis of BO. *Exh. P, Pue Depo* at 73:5-74:15, 92:24-93:17.

19 **2. Dr. Egilman failed to address the likelihood that Mr.**  
 20 **Newkirk’s disease was actually caused by his exposure to**  
 21 **cigarette smoke.**

22 “[W]here a defendant points to a plausible alternative cause and the doctor  
 23 offers no explanation for why he or she has concluded that it was not the sole  
 24 cause, that doctor’s methodology is unreliable.” *Henricksen*, 605 F.Supp.2d at

1 1162. Here, Dr. Egilman ignored the single most plausible explanation for Mr.  
2 Newkirk's disease: his significant smoking history. Dr. Egilman's only mention of  
3 this history is one sentence which reads "[h]e smoked from 1979-1986 about 1 to  
4 1.5 packs a day." *Exh. B, Egilman Report* at 3. This sentence appears in Dr.  
5 Egilman's overview of Mr. Newkirk's medical history; nowhere in Dr. Egilman's  
6 actual opinions does he address the possibility that Mr. Newkirk's disease was  
7 caused by his smoking history. *Id.*

8 A study conducted in 2005 looked at the effects of smoking an average of  
9 ten cigarettes a day (half a pack) for 2-5 years, or 1-2.5 pack years, on PFT tests.  
10 *Exh. KK, Bajentri Study*. The study found that there was a significant reduction in  
11 lung function in the smokers. *Exh. KK, Bajentri Study*. The study also showed  
12 that a history of 1-2.5 pack years "leads to a definite tendency to narrowing of both  
13 the large and the small airways." *Exh. KK, Bajentri Study*. In addition, data  
14 presented by the EPA found that non-smokers exposed to second-hand tobacco  
15 smoke have a 2.5% lower FEV<sub>1</sub> than those who are not exposed. *Exh. XX, Hessel*  
16 *Report* at 32.

17 It is difficult ascertain an individual's true smoking history because of the  
18 degree of self-reporting that goes into such an endeavor. Plaintiffs' pulmonology  
19 expert, Dr. Pue, admitted that he has no way to determine whether an individual is  
20 accurate in reporting their smoking history. *Exh. P, Pue Depo* at 49:21-50:3. Mr.  
21 Newkirk's self-reported smoking history includes a starting year sometime  
22 between 1977 and 1980 and lasting until anywhere from 1984 to 1988, depending  
23 on which history he gave and when. *Exh. LL, Windrose Patient Information Form*



1 at 2 (started in 1977); *Exh. 00, Williams Notes 7/2/03* (started in 1980); *Exh. HHH,*  
2 *Leavitt Letter* (quit in 1984); *Exh. MM, Sleep Disorders Questionnaire at 2* (quit in  
3 1988). Likewise, the quantity of cigarettes Mr. Newkirk reported having smoked  
4 each day varied from 1 ½ packs to 2 ½ packs. *Exh. NN, Windrose Progress notes*  
5 *1/29/08* (smoked 1 ½ packs a day); *Exh. OO, Williams Notes 7/2/03* (smoked 2 - 2  
6 ½ packs a day). Thus, on the high end he had the equivalent of 25 pack years (10  
7 years at 2 ½ packs a day) and on the low end he had the equivalent of 6 pack years  
8 (4 years at 1 ½ packs a day). This enormous discrepancy has not been addressed  
9 by Dr. Egilman in any manner.

10 Mr. Newkirk also had significant second-hand smoke exposure. He owned  
11 and operated a bar for two years where he was constantly surrounded by smoke.  
12 *Exh. PP, Newkirk Depo at 23:23-25:3.* He worked at the bar approximately ten  
13 hours a day, six-seven days a week. *Id. at 26:25-27:13.* This is not even  
14 mentioned in Dr. Egilman's report. *Exh. B, Egilman Report.* Furthermore, Mr.  
15 Newkirk's wife smoked not only the entire time he smoked, but she continued to  
16 smoke after he quit, and smokes to this day. *Exh. PP, Newkirk Depo at 53:10-12,*  
17 *61:11-22, 62:15-25.* While Mr. Newkirk claims that she only smokes outside now,  
18 this practice is of recent advent and her earlier smoking was also a significant  
19 source of second-hand smoke to Mr. Newkirk for many years. *Id. at 61:11-22,*  
20 *62:25-63:4.* Defendants' expert pulmonologists have opined that Mr. Newkirk has  
21 chronic obstructive pulmonary disease ("COPD") caused by his smoking history.  
22 *Exh. YY, Weill Report; Exh. SS, Utell Report; Exh. AAA, Bruya Report.* Dr.

1 Egilman cannot plausibly opine to a reasonable degree of certainty that Mr.  
2 Newkirk's disease is not a result of his smoking history.<sup>7</sup>

3 **3. Dr. Egilman failed to address the likelihood that Mr.**  
4 **Newkirk's lung disease was caused by his gastroesophageal**  
5 **reflux.**

6 A recent study found that gastroesophageal reflux ("GERD") may be  
7 associated with the development of BOS in post-transplant patients. *Exh. GGGG,*  
8 *Gastroesophageal Reflux in Bronchiolitis Obliterans Syndrome: A New*  
9 *Perspective* at 870. Mr. Newkirk has been diagnosed with GERD. *Exh. FF, Elmer*  
10 *Report.* Dr. Egilman failed to address the possibility that Mr. Newkirk's lung  
11 disease may have been caused by GERD. *Exh. B, Egilman Report.*

12 **V. CONCLUSION**

13 Dr. Egilman failed to apply the proper methodology necessary for  
14 establishing specific causation: he did not demonstrate that MWPC vapors can  
15 cause BO or at what exposure level, he did not demonstrate that Mr. Newkirk was  
16 exposed to a sufficient level of MWPC vapors to cause his BO, and he did not  
17 adequately rule out other possible causes of Mr. Newkirk's disease. For these

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19 <sup>7</sup> In addition, Dr. Egilman did not address the issue of idiopathic, or unknown,  
20 causes of BO, which account for a portion of the diagnosed cases. *Exh. GGG,*  
21 *Miscellaneous Causes of Bronchiolitis: Inhalational, Infectious, Drug-Induced and*  
22 *Idiopathic*, at 571. In order to result in an admissible conclusion, Dr. Egilman's  
23 analysis should rule out reasonable alternative causes of Mr. Newkirk's disease,  
24 including idiopathic causes. *Henricksen*, 605 F.Supp.2d 1162.

1 reasons, Dr. Egilman's specific causation opinion is not reliable or relevant and  
2 should be excluded under Rule 702 and *Daubert*.

3 DATED this 8th day of March, 2010.

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 8th day of March, 2010, I electronically filed the foregoing MEMORANDUM OF AUTHORITIES IN SUPPORT OF DEFENDANTS' JOINT MOTION TO EXCLUDE THE SPECIFIC CAUSATION TESTIMONY OF PLAINTIFFS' EXPERT DR. EGILMAN with the Clerk of the Court using the CM/ECF System, which will send email notification of such filing to the following:

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